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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,543	01/17/2002	David E. Lam		7769

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,543	Applicant(s) LAM ET AL.	
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9 and 14-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 14-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/02, 10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-2, 4-9, 14-52 are currently pending and are present for examination.

Election/Restrictions

Applicant's election of Group XXIII in the reply filed on 5-10-04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only. It is however noted by the Examiner that applicants depict the figures in the figures description as Fig 1A to 1X. However, no such description can be found on the figures. Furthermore the sequences depicted in the figures lack SEQ ID NO.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is particularly noted that applicants fail to provide the SEQ ID NO for sequences depicted in the figures either in the figures or in the respective figure description. See particularly 37 CFR 1.821(d).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 35, 44-52 are all rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example, claim 19 and 35 are directed to polynucleotide/polypeptide having a 97% sequence identity. Examiner was unable to find support for said per cent sequence identity in the specification. Similarly, claims 44-52 are all drawn to different methods of using the polypeptide. However Examiner was unable to find support for any of said claimed methods in the specification. Therefore, above claims have been rejected as introducing new subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 recites the phrase "into a fuel or a chemical". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to what types of

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“fuels” and “chemicals” are encompassed by the above phrase. A perusal of the specification did not yield a specific definition for the above phrase.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 recites the phrase “produces an animal feed”. The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how just hydrolysis of CMC cellulose or glycosidic cleavage of a chemical bond produces an animal feed. A perusal of the specification did not yield a specific definition for the above phrase.

Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 47 recites the phrase “waste treatment”. The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to what types of “wastes” are encompassed by the above phrase. A perusal of the specification did not yield a specific definition for the above phrase.

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 49 recites the phrase “polypeptide further comprises a textile”. The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how the polypeptide can further comprise a textile. It appears that applicants meant to recite a

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“composition of the polypeptide further comprising a”. If that is the case, amending the claim accordingly (provided there is ample support for the amendment in the specification) would overcome the above rejection.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 50 recites the phrase “polypeptide further comprises a feed”. The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how the polypeptide can further comprise a textile. It appears that applicants meant to recite a “composition of the polypeptide further comprising a”. If that is the case, amending the claim accordingly (provided there is ample support for the amendment in the specification) would overcome the above rejection.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 51 recites the phrase “polypeptide further comprises a detergent”. The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how the polypeptide can further comprise a textile. It appears that applicants meant to recite a “composition of the polypeptide further comprising a”. If that is the case, amending the claim accordingly (provided there is ample support for the amendment in the specification) would overcome the above rejection.

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Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites the phrase "polypeptide further comprises a juice or a brew". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how the polypeptide can further comprise a textile. It appears that applicants meant to recite a "composition of the polypeptide further comprising a". If that is the case, amending the claim accordingly (provided there is ample support for the amendment in the specification) would overcome the above rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-9, 14-19, 21-22, 24-30, 32-35, 38-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an endoglucanase of SEQ ID NO:46, a polynucleotide having the SEQ ID NO:45 encoding the same and vectors and host cells comprising said polynucleotide, does not reasonably provide enablement for any such polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or a polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising 15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells

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comprising said polynucleotides and method of making said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 2, 4-9, 14-19, 21-22, 24-30, 32-35, 38-52 are so broad as to encompass any endoglucanase polypeptide that has either 70%, 90%, 95%, or 97% sequence identity with SEQ ID NO:46 or polypeptides comprising 30 or 50 amino acids of a polypeptide that is 70% identical to SEQ ID NO:46 or cellulase polypeptides comprising 30 or 50 consecutive amino acids of SEQ ID NO:46 or a polynucleotide having a nucleotide sequence which is either 70%, 90%, 95%, 97% identical to SEQ ID NO:45 or a probe comprising 15, 25, 35, or 50 nucleotides of a polynucleotide having a sequence that is at least 70% identical to SEQ ID NO:45, vectors and host cells comprising said polynucleotides and method of making said polypeptides.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard

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to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only a single endoglucanase. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides and polynucleotides. The specification is limited to teaching the use of SEQ ID NO: 45 and 46 as a endoglucanase but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

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The specification does not support the broad scope of the claims which encompass all modifications and fragments of any endoglucanase polypeptide and polynucleotide encoding the same because the specification does not establish: (A) regions of the protein structure which may be modified without affecting its activity; (B) the general tolerance of endoglucanases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including endoglucanases with an enormous number of amino acid modifications to SEQ ID NOS:46. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide having endoglucanase activity and the polynucleotides encoding the same is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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These claims are directed to a genus of polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or 30 to 50 amino acids of SEQ ID NO:46. The specification does not contain any disclosure of the structure of all such sequences included in the claimed genera. The genus of polypeptides claimed is a large variable genus with the potentiality of having different structures. Therefore, many structurally distinct polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus (i.e., that of SEQ ID NO:46) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by sequence or a recitation of structural features common to members of the genus, **which features constitute a substantial portion of the genus**. The recited structural feature of the genus (i.e., polypeptides having endoglucanase activity and comprising 30 or 50 amino acids of a polypeptide that has 70% sequence identity to SEQ ID NO:46 or polypeptides comprising 30 to 50 amino acids of SEQ ID NO:46) does not constitute a substantial portion of the genus as the remainder of the structure of such polypeptide having endoglucanase activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 31 is directed to structure conservative variant polypeptide corresponding to SEQ ID NO:46. Claim 31 rejected under this section of 35 USC 112 because the claim is directed to a genus of polypeptides derived from SEQ ID NO:46 that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:46 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The specification does not contain any disclosure of the function of all the polypeptide sequences derived from SEQ ID NO:46, including fragments and structure conservative variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules comprising 15, 25, 35, or 50 contiguous nucleotides of a nucleic acid sequence having at least 70% sequence identity to SEQ ID NO:45.

The specification does not contain any disclosure of the function of all DNA sequences that are encompassed by the claim. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-9, 14-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Bylina(a) et al. (US 6368844, 4-9-2002) or Bylina(b) et al. (US 2002/0155550 A1, 10-24-02) or Short et al. (US 2002/0078397 A1, 4-24-03). This rejection is based upon the public availability of a printed publications/patent. Claims 1-2, 4-9, 14-52 of the instant application are drawn to a recombinant polynucleotide with SEQ ID NO:45 encoding an endoglucanase or cellulase enzyme having an amino acid sequence SEQ ID NO:46, several types of variants of the same, vectors and host cells comprising said polynucleotides, and methods of using said polynucleotide and polypeptide in various processes. All three of the above references having an effective priority date that precedes the filing date of the instant application disclose polynucleotide which is 100% identical to SEQ ID NO:45 encoding a polypeptide that is 100% identical to SEQ ID NO:46 (see enclosed sequence alignments) and all the related methods of using them, thereby anticipating claims 1-2, 4-9, 14-52 as written.

Conclusion

None of the claims are allowable.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'Manjunath N. Rao', with a stylized flourish at the end.

Manjunath N. Rao
July 15, 2004